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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/594,361

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Jon Erik Braenden

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EXAMINER

VALENROD, YEVGENY

ART UNIT

PAPER NUMBER

1621

MAIL DATE

DELIVERY MODE

02/03/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/594,361	Applicant(s) BRAENDEN ET AL.	
	Examiner YEVEGENY VALENROD	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 20-23,28,29,32,33,41-48 and 50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19,24-27,30,31,34-40 and 49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/28/08, 08/06/07, 09/26/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The following is the first office action on the merits in application # 10/594, 361.

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-19, 24-27, 30, 31, 34-40 and 49, in the reply filed on 10/28/08 is acknowledged.

Claims 20-23, 28, 29, 32, 33, 41-48 and 50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/28/09.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 15 recites the limitation directed to sulfonic acid derivatives in lines 2-4 of the claim. There is insufficient antecedent basis for this limitation in the claim. Claims 13 and 14, from which 15 depends limit the acid to only sulfonic acid.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-19, 24-27, 30, 31, 34-40 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giersckky et al (US 6,034,267) in view of Berge et al. (*Journal of Pharmaceutical Sciences*, **1977**, 66, page 1).

Scope of prior art

Giersckky et al. teach esters of 5-aminolevulinic acid and acid addition salts thereof. The esters of 5-ALA include alkyl and aryl phenyl substituted alkyl esters (column 2, lines 51-column 3, line 2). Acid addition salts include organic and inorganic acids including sulfuric acid (column 4, lines 40-46). Giersckky et al. also teach Pharmaceutical compositions comprising 5-ALA or salts thereof comprising the 5-ALA and pharmaceutically acceptable carriers and excipients (column 5, lines 11-15). Said compositions are described as having utility as medicaments (Column 5, lines 16-19). Also described, are formulations comprising photosensitizing agents, chelating agents and surface penetrating agents (column 7, lines 12-40).

Difference between instant claims and prior art

Prior art fails to provide an example of 5-ALA derivative acid addition salt according to the instant claims.

Also prior art fails to explicitly list sulfonic acid derivatives as acceptable acids.

Secondary reference

Berge et al teach methyl sulfate as a pharmaceutically acceptable anion (page 2, Table 1)

Obviousness

One skilled in the arts would find it obvious to practice the invention of Giersckky et al. as described in the patent specification. One would find it obvious to select any disclosed ester of 5-ALA and formulate it into a salt using organic or inorganic acid. Sulfuric acid is specifically listed in Giersckky and methanesulfonic acid is a known pharmaceutically acceptable anion. Selecting a known anion for a pharmaceutically active salt is obvious absent unexpected results.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

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F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-19, 24-27, 30, 31, 34-40 and 49 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 10 and 19 of U.S. Patent No. 7,287,646. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Instant claims differ from claims of '646 in that the instant claims are directed to salts of 5-ALA, while claims of '646 are directed to free bases.

Obviousness

Its obvious to prepare an acid salt of a free base where the free base is a known pharmaceutically active agent. Preparing a salt is known to alter properties such as solubility and stability of a pharmaceutically active agent.

Claims 1-19, 24-27, 30, 31, 34-40 and 49 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 7 of U.S. Patent No. 7,217,736. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Instant claims differ from claims 1 and 7 of '736 in that the instant claims are directed to a salt of 5-ALA while the claims of '736 are directed to free bases.

Obviousness

Its obvious to prepare an acid salt of a free base where the free base is a known pharmaceutically active agent. Preparing a salt is known to alter properties such as solubility and stability of a pharmaceutically active agent.

Conclusion

Claims 1-50 are pending.

Claims 20-23, 28, 29, 32, 33, 41-48 and 50 are withdrawn

Claims 1-19, 24-27, 30, 31, 34-40 and 49 are rejected

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yevgeny Valenrod whose telephone number is 571-272-9049. The examiner can normally be reached on 8:30am-5:00pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Yevgeny Valenrod/

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